NIOSH Comments to DOL

COMMENTS OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH ON THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S NOTICE OF PROPOSED RULEMAKING ON OCCUPATIONAL EXPOSURE TO ASBESTOS, TREMOLITE, ANTHOPHYLLITE, AND ACTINOLITE

29 CFR Parts 1910 and 1926
Docket No. H-033d

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

4/9/90

INTRODUCTION

The following is the National Institute for Occupational Safety and Health (NIOSH) response to the Occupational Safety and Health Administration (OSHA) notice of proposed rulemaking to remove nonasbestiform tremolite, anthophyllite, and actinolite from the asbestos standard. Specifically, OSHA has proposed to lift the administrative stay, remove 29 CFR 1910.1101, and amend the revised asbestos standards [29 CFR 1910.1001; 29 CFR 1926.58] to remove nonasbestiform tremolite, anthophyllite, and actinolite from their scope.

NIOSH is concerned that deleting coverage of cleavage fragments from nonasbestiform tremolite, anthophyllite and actinolite from the standard poses a health risk for exposed workers. On June 21, 1984, NIOSH testified at the OSHA public hearings on occupational exposure to asbestos and presented supporting evidence that there is no safe concentration for exposure to asbestos [NIOSH 1984]. NIOSH stated that not even the lowest exposure limit for asbestos could assure all workers of absolute protection from exposure-related cancer. This conclusion was consistent with previous positions taken by NIOSH in the 1976 criteria document on asbestos and the joint NIOSH/OSHA report of 1980 [NIOSH 1976; NIOSH/OSHA 1980]. In the NIOSH/OSHA report, NIOSH also reaffirmed its position that there is no scientific basis for differentiating health risks between types of asbestos fibers for regulatory purposes. In its 1984 testimony, NIOSH urged that the goal be to eliminate asbestos exposure [NIOSH 1984]. Where asbestos exposure cannot be eliminated, it should be limited to the lowest concentration possible.

When recommending an occupational exposure limit in its 1984 testimony, NIOSH acknowledged the limitations imposed by currently accepted methods of sampling and analysis. NIOSH concluded that for regulatory purposes, phase contrast microscopy was still the most practical technique for assessing asbestos exposures when using the criteria given in NIOSH Analytical Method 7400 [NIOSH 1989a]. NIOSH also recognized that phase contrast microscopy lacked specificity when asbestos and other fibers occurred in the same environment, and that it might be necessary to analyze air samples by electron microscopy where both electron diffraction and microchemical analysis can be used to help identify the type of mineral.

REVIEW OF THE LITERATURE BY OSHA

In its review of the health literature, OSHA has acknowledged the difficulties in interpreting the health effects evidence for the nonasbestiform minerals. These difficulties result partly from the confusion over mineralogic definitions and the ways in which these definitions have been used to characterize mineral particles on a microscopic level for epidemiologic studies and animal bioassays. OSHA's review of the mineralogic data concluded that the amphibole minerals form in a continuum of habits ranging from granular to fibrous to the extremely fibrous and thin asbestiform habit. They further noted that often, no exact line can be drawn between the nonasbestiform acicular habits and the asbestiform habit. OSHA also stated that at the microscopic level, acicular cleavage fragments (nonasbestiform by mineralogic definition) are frequently indistinguishable from mineral fibers derived from commercial asbestos fibers.

NIOSH concurs with OSHA's review of the scientific literature and maintains that there is equivocal evidence suggesting that cleavage fragments of nonasbestiform tremolite, anthophyllite, and amosite may cause cancer and other health impairments, and that 1) present analytical technologies cannot distinguish between asbestiform fibers and nonasbestiform cleavage fragments, and 2) data indicate that fiber dimension and durability may be more predictive of the carcinogenic potential than physiochemical properties. The following comments address specific areas of the OSHA literature review.

Exposure to Nonasbestiform Minerals

OSHA has evaluated various reports that reviewed the health effects of exposure to nonasbestiform minerals [Bailey 1988; Environmental Health Associates, Inc. 1988; Boehlecke 1988; Cooper 1988; Balmes and Rempel 1989; Nicholson 1989]. Their opinion is that the evidence suggests the existence of a possible carcinogenic hazard and other impairing noncarcinogenic adverse health effects from exposure to these minerals. OSHA stated further that evidence indicates mixed exposures of the asbestiform and nonasbestiform minerals have caused lung cancer and other asbestos-related diseases in workers employed in the mining of talc [Kleinfeld et al. 1974; Kleinfeld et al. 1967; Brown et al. 1979] and vermiculite [McDonald et al. 1986; Amandus and Wheeler 1987].

Fiber Characteristics

Several studies submitted to the docket and reviewed by OSHA [Stanton et al. 1981; Stanton et al. 1977; Wagner 1986] provide evidence that fiber dimension is an important factor in the etiology of asbestos-related disease. Stanton et al. [1977] concluded from their animal study that the carcinogenicity of fibers depends on dimension and durability rather than physiochemical properties; they emphasized that all respirable fibers should be viewed with caution. Other reports submitted to OSHA [Harington 1981; Pott 1980; Wagner et al. 1980; Wright and Kuschner 1977; Bertrand and Pezerat 1980] support this hypothesis. In an analyses of Stanton's data by Bertrand and Pezerat [1980] and Bonneau et al. [1986], a high correlation was found to exist between aspect ratio and tumor incidence, and the observed increase in tumor development began with exposure to fibers having aspect ratios of about 3:1 to 5:1.

In the proposed rule, OSHA concluded the following from their review of the epidemiologic and animal data:

> "There is insufficient evidence to conclude that nonasbestiform tremolite, anthophyllite, and actinolite cleavage fragments present a health risk similar in magnitude or type to fibers of their asbestiform counterparts. However, the positive evidence of

> carcinogenicity of their asbestiform counterparts and other durable nonasbestos minerals, in conjunction with evidence that the carcinogenic process is associated with fiber characteristics (i.e., size, shape, durability) possessed by nonasbestiform tremolite, anthophyllite, and actinolite particles, do raise questions as to the toxic potential of cleavage fragments of nonasbestiform minerals."

NIOSH ASSESSMENT OF THE SCIENTIFIC LITERATURE

NIOSH concurs with OSHA's review and assessment of the epidemiologic and animal data submitted to the docket and finds the evidence sufficient to conclude that nonasbestiform tremolite, anthophyllite, and actinolite cleavage fragments present a health risk similar in magnitude to fibers of their asbestiform analogs.

Epidemiology

Reviews of epidemiologic studies submitted to OSHA on workers exposed to nonasbestiform cleavage fragments have found equivocal evidence of a health risk [Nicholson 1989; Balmes and Rempel 1989]. Other epidemiologic studies [Brown et al. 1979; Kleinfeld et al. 1974; Kleinfeld et al. 1967, McDonald et al. 1986; Amandus and Wheeler 1987] cited by OSHA have provided clear evidence of an increase in lung cancer and other asbestos-related diseases in talc and vermiculite workers with mixed exposures to the asbestiform and nonasbestiform minerals.

Animal Studies

As stated by OSHA, most of the experimental animal carcinogenicity studies with mineral fibers have been conducted by intrapleural or intraperitoneal administration. These studies [Stanton et al. 1977; Stanton et al. 1981; Wagner et al. 1982; Muhle et al. 1987; Pott et al. 1974; Pott et al. 1987] have provided the strongest evidence that the carcinogenic potential depends on the size of the mineral particle length and diameter. The consistency in tumorigenic responses observed for various mineral particles of the same size suggests that the chemical composition of these particles may not be a critical factor in carcinogenic potential. Literature reviews by Lippmann [1988] and Pott et al. [1987] enhance the hypothesis that any mineral particle can induce cancer and mesothelioma if it is sufficiently durable to be retained in the lung and if it has the appropriate aspect ratio and dimensions. Similarly, Wagner [1986] concluded that all mineral particles of a specific diameter and length size range may be associated with development of diffuse pleural and peritoneal mesotheliomas.

Reviews by Other Scientific Bodies

In their review of the health risks from exposure to asbestos and other mineral fibers, the National Resource Council concluded the following:

> Although data reported by most investigators show an increased risk of mesothelioma after exposure to long, thin fibers, in comparison to short, thick fibers, there does not appear to be a critical length below which fibers have no carcinogenic potential [National Research Council 1984].

The American Thoracic Society (ATS) concluded the following in their review of the health data on exposures to asbestiform and nonasbestiform tremolite:

> If the mechanism(s) of asbestos induced or promoted carcinogenesis were clearly understood, in both mineralogical and biological terms, then we could proceed easily to distinguish what is truly asbestiform and nonasbestiform for regulatory purposes. However, because such clarity of understanding is not apparent, it would seem prudent public health policy to use an inclusive, rather than an exclusive, definition of asbestos [ATS 1989].

Conclusion

On the basis of the available epidemiologic and animal data, and the lack of sufficient data to the contrary, NIOSH concludes for regulatory purposes that cleavage fragments of the appropriate aspect ratio and length from the nonasbestiform minerals should not be considered less hazardous than fibers from the asbestiform minerals independent of the mineralogic habit. Such prudent public health practices are necessary until sufficient exposure data are collected to demonstrate the absence of risk from exposures to these nonasbestiform minerals.

NIOSH finds no scientifically valid health evidence for removing from the asbestos standard cleavage fragments that (1) become airborne when nonasbestiform tremolite, anthophyllite, and actinolite are mined, milled and used and (2) meet the microscopic definition of a fiber. Deletion of these nonasbestiform minerals from the standard would pose a potentially serious health risk to exposed workers and would compromise the protection afforded to workers with mixed exposures to the asbestiform and nonasbestiform minerals, because it is not possible to distinguish between asbestos fibers and cleavage fragments from their nonasbestiform analogs with presently available analytical methods. The risk of cancer from exposure to asbestos and the potential risk of cancer from their nonasbestiform analogs warrant limiting exposures to these minerals to the lowest feasible concentration.

Furthermore, NIOSH is concerned about the potentially serious health hazard that could be posed to exposed workers if users of crushed stone or aggregate rock, or any other mineral commodity that can be contaminated with these minerals are exempted from initial monitoring and labeling requirements of the asbestos standard. Many of the mines and quarries where these commodities are extracted are located in areas containing igneous or metamorphic rocks where both asbestiform and nonasbestiform exposures can occur [Bartlett 1988; Campbell 1988]. The existence of this contamination is evident from exposure data collected by the Mine Safety and Health Administration (MSHA) at selected stone and sand/gravel mine sites [Consad Research Corporation 1989]. These data revealed airborne fiber concentrations (total of 60 samples) that ranged from 0.18 to 15.60 fibers/cc when analyzed by phase contrast microscopy and using the criteria for a fiber as being any particle with a $\geq$ 3:1 and length > 5 μm. Asbestos fibers were identified in 2 of 60 samples, and nonasbestiform tremolite, anthophyllite, and actinolite cleavage fragments were found in 7 of 60 samples when analyzed by electron microscopy. For these 9 samples, exposure concentrations of asbestos fibers and nonasbestiform cleavage fragments were determined by electron microscopy, which indicated concentrations of 0.01 to 1.2 fibers/cc. Similar exposure concentrations (0.02 to 0.9 fibers/cc) have been reported by the Fairfax County Health Department [Dusek and Yetman 1990] for workers exposed to asbestiform and nonasbestiform tremolite and actinolite during earth and rock removal operations in Fairfax County, Virginia.

Because many of the crushed stone and aggregate rock mines and quarries are located in areas of the country where the asbestiform and nonasbestiform minerals occur, NIOSH is concerned about the potential contamination of these minerals in mining commodities that are used in numerous industrial applications. The use of these commodities in the workplace with minimal or no engineering controls in place could pose a serious health risk to workers. NIOSH has identified from the National Occupational Survey (NOES) data the potential for exposure to talc/tremolite/anthophyllite in forty-one 2-digit Standard Industrial Classification (SIC) codes in which 67,678 industries and over 1 million workers could be potentially exposed [NIOSH 1983]. Of the forty-one 2-digit SIC codes, 25 were identified as having exposure to tremolite (4,517 industries and 46,980 workers). An analysis of the various talcs reported in the NOES trade name data base indicated that the talc observed in these industries could be contaminated with up to 50% tremolite and 10% anthophyllite.

NIOSH does not suggest that any evaluation of bulk samples or settled dust samples collected at mines or quarries where asbestiform and nonasbestiform minerals occur can provide an adequate assessment as to the presence of these minerals because they can occur sporadically at the mine site. Also, NIOSH is unaware of any analytical methods that can be used routinely to differentiate between airborne exposures to asbestos fibers and nonasbestiform cleavage fragments. The inability to microscopically distinguish between fibers and cleavage fragments raises serious concerns about excluding the nonasbestiform minerals from the asbestos standard. Because of these uncertainties, exclusion of these minerals from the asbestos standard will present enforcement difficulties when the source of the airborne exposure is unknown or when the exposure involves mixed mineral types. The analytical limitations inherent in differentiating between respirable asbestos fibers and the cleavage fragments of the nonasbestiform analogs, and the uncertainty of the adverse health effects further support the need to include the nonasbestiform minerals in the asbestos standard.

To clarify the definitions of minerals, NIOSH has incorporated the appropriate mineralogic nomenclature in its recommended standard for asbestos. This clarification in nomenclature permits the inclusion of cleavage fragments from the nonasbestiform habits of the asbestos minerals. The NIOSH definition of minerals to be included in the regulatory standard for asbestos is as follows:

> Asbestos is defined as chrysotile, crocidolite, amosite (cummingtonite-grunerite), anthophyllite, tremolite, and actinolite. The nonasbestiform habits of the serpentine minerals antigorite and lizardite, and the amphibole minerals contained in the series cummingtonite-grunerite, tremolite-ferroactinolite, and glaucophane-riebeckite shall also be included provided they meet the criteria for a fiber as ascertained on a microscopic level. A fiber is defined as a particle with an aspect ratio of 3:1 or larger and having a length > 5 μm.
>
> The determinations of airborne fiber concentrations are made microscopically and can be determined using NIOSH Method 7400 [NIOSH 1989a], or its equivalent. In those cases when asbestos and other mineral fibers occur in the same environment, then Method 7400 can be supplemented by the use of NIOSH Method 7402 [NIOSH 1989b], or its equivalent, to improve specificity of the mineral determination.

A glossary of terms is given in Attachment A and provides the basis for the mineral terminology used in the NIOSH regulatory definition for asbestos.

NIOSH maintains that prudent public health practice dictates the use of appropriate labeling and initial exposure monitoring when workers are potentially exposed to asbestos fibers or cleavage fragments from their nonasbestiform analogs. Such prudent public health practices are necessary until sufficient exposure data are collected to demonstrate the absence of risk from exposures to these nonasbestiform minerals.

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Attachment A

GLOSSARY OF TERMS

ASBESTOS

Asbestos is a generic term for a number of silicate minerals with a fibrous crystalline structure.

The quality of commercially used asbestos depends on the mineralogy of the asbestiform variety, the degree of fiber development, the ratio of fibers to acicular crystals or other impurities, and the length and flexibility of the fibers. The asbestiform varieties of these minerals can be found in both the amphibole and serpentine mineral groups. The asbestiform varieties occur in veins or small veinlets within rock containing or composed of the common (nonasbestiform) variety of the same mineral. The major asbestiform varieties of minerals used commercially are chrysotile, tremolite-actinolite asbestos, cummingtonite-grunerite asbestos, anthophyllite asbestos, and crocidolite. Asbestos is marketed by its mineral name (e.g., anthophyllite asbestos), its variety name (e.g., chrysotile or crocidolite), or its trade name (e.g., Amosite).

SERPENTINE MINERALS

The serpentine minerals belong to the phyllosilicate group of minerals. The commercially important variety is chrysotile, which originates in the asbestiform habit. Antigorite and lizardite are two other types of serpentine minerals that are structurally distinct. The fibrous form of antigorite is called picrolite.

Chrysotile: Chrysotile generally occurs segregated as parallel fibers in veins or veinlets and can easily separate into individual fibers or bundles. Often referred to as "white asbestos," it is used commercially for its good spinnability in the making of textile products, and as an additive in cement or friction products.

AMPHIBOLE MINERALS

Minerals in the amphibole group are widely distributed in the earth's crust in many igneous or metamorphic rocks. In some instances, the mineral deposits contain sufficient quantities of the asbestiform minerals to be economically minable for commercial use. The minerals and mineral series of the amphibole group have variable compositions with extensive elemental substitutions. They are found in forms ranging from massive to fibrous. The most common commercially exploited asbestiform varieties of this mineralogical group include crocidolite, amosite, anthophyllite, tremolite, and actinolite. Crocidolite, amosite, and anthophyllite are selectively mined for commercial use, whereas tremolite and actinolite are most often found as a contaminant in other mined commodities such as talc and vermiculite. The amphiboles have good thermal and electrical insulation properties, and they have moderate to good resistance to acids.

Crocidolite: Crocidolite is from the fibrous habit of the mineral riebeckite and is in the mineral series glaucophane-riebeckite, in which both asbestiform and nonasbestiform habits can occur. This mineral type is commonly referred to as "blue asbestos."

Amosite: Amosite is the commercial term derived from the acronym "Asbestos Mines of South Africa." Amosite is in the mineral series cummingtonite-grunerite,* in which both asbestiform and nonasbestiform habits of the mineral can occur. This mineral type is commonly referred to as "brown asbestos."

Anthophyllite: Anthophyllite can occur in both the asbestiform and nonasbestiform mineral habits. The asbestiform variety is often referred to as anthophyllite asbestos.

Tremolite: Tremolite can occur in both the asbestiform and nonasbestiform mineral habits and is in the mineral series tremolite-ferroactinolite*. The asbestiform variety is often referred to as tremolite asbestos.

Actinolite: Actinolite can occur in both the asbestiform and nonasbestiform mineral habits and is in the mineral series tremolite-ferroactinolite.* The asbestiform variety is often referred to as actinolite asbestos.

Asbestiform habit: A specific type of mineral fibrosity in which the growth is primarily in one dimension and the crystals form naturally as long, flexible fibers. Fibers can be found in bundles that can be easily separated into smaller bundles or ultimately into fibrils.

Cleavage fragments: A fragment produced by the breaking of crystals in directions that are related to the crystal structure and are always parallel to possible crystal faces. Minerals with perfect cleavage can produce perfect regular fragments. Amphiboles with prismatic cleavage will produce prismatic fragments. Note: These fragments can be elongated and may meet the definition of a fiber upon microscopic examination.

*Mineral series such as cummingtonite-grunerite and tremolite-ferroactinolite are created when one cation is replaced by another in a crystal structure without significantly altering the structure. There may be a gradation in the structure in some series, and minor changes in physical characteristics may occur with elemental substitution. Usually a series has two end members with an intermediate substitutional compound being separately named, or just qualified by being referred to as members of the series. Members of the tremolite-ferroactinolite series are hydroxylated calcium-magnesium, magnesium-iron, and iron silicates, with the intermediate member of this series being named actinolite.

Fiber: An acicular single crystal or similarly elongated polycrystalline aggregate particles. Such particles have macroscopic properties such as flexibility, high aspect ratio, silky luster, and axial lineation. These particles have attained their shape primarily because of manifold dislocation planes that are randomly oriented in two axes but parallel in the third. Note: Upon microscopic examination, only particles that have a 3:1 or greater aspect ratio are defined as fibers. Other macroscopic properties used to define fibers cannot be ascertained for individual particles examined microscopically.

Fibril: A single fiber that cannot be separated into smaller components without losing its fibrous properties or appearances.

Nonasbestiform habit: Each of the six commercially exploited asbestiform minerals also occurs in a nonasbestiform mineral habit. These minerals have the same chemical formula as the asbestiform variety, but they have crystal habits where growth proceeds in two or three dimensions instead of one dimension. When milled, these minerals do not break into fibrils but rather into fragments resulting from cleavage along the two or three growth planes. Particles thus formed are referred to as cleavage fragments and can meet the definition of a fiber for regulatory purposes.

Mineral: A homogeneous, naturally occurring, inorganic crystalline substance. Minerals have distinct crystal structures and variation in chemical composition, and are given individual names.

Mineral series: A mineral series includes two or more members of a mineral group in which the cations in secondary structural position are similar in chemical properties and can be present in variable but frequently limited ratios (e.g., cummingtonite-actinolite). The current trend in referring to a mineral series is to simplify long series names by using the mineral name of only one (end or intermediate) member (i.e., tremolite-actinolite-ferroactinolite).

Mineral variety: The variety distinguishes minerals that are conspicuously different from (1) those considered normal within the common crystallization habits, polytypes, and other structural variants, and (2) those with different physical properties such as color.

Varieties are named by mineralogists, miners, gemologists, manufacturers of industrial products, and mineral collectors.

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